

REMARKS

In the aforesaid Office Action, claim 31 was objected to, claims 26 was rejected under 35 USC 112, second paragraph, claims 26, 28-29, 34 and 35 were rejected under 35 USC 102(b) as being anticipated by Wang et al. (US 5,556,383), and claims 30-33, 36 and 37 were rejected under 35 USC 103(a) as being unpatentable over Wang et al. alone. Claims 26 and 28-37 are pending.

The Examiner states that Wang et al. discloses a balloon having radial distention % or shrinkage % from the inflated outer diameters of the balloons to the inner diameters of the molds at ambient temperature at 4.2% (example 1) or 3.2% (example 2) when inflated from 88 psi to 132 psi.

However, contrary to the Examiner's assertion, Wang et al. discloses the radial distension or growth of the inflated outer diameter of the balloon, and not a radial shrinkage of the inflated outer diameter of the balloon as set forth in Applicant's claim 26. Specifically, Wang et al. discloses that the inflated outer diameter of the finished balloon was measured at incrementally increasing inflation pressures until the balloon burst, and the results given in Table 1. The percent distension referred to by the Examiner (i.e., 4.2% for Example 1, and 3.2% for Example 2) is the radial growth of the balloon outer diameter expressed as a percentage as the inflation pressure is increased from 88 psi to 132 psi (i.e., the outer diameter increased by 4.2% in Example 1 as the inflation pressure within the balloon was increased from 88 psi to 132 psi).

In contrast, Applicant's claim 26 is directed to a dimensionally stable balloon having radial shrinkage of less than 10%, the radial shrinkage being defined as the difference between a first inflated outer diameter of the balloon after formation by the present process and a second inflated diameter of the balloon as part of a catheter system after exposure to a shrinking treatment which causes the radial shrinkage. Thus, between formation of the balloon by the present process (which includes heat setting the balloon in a balloon mold with a heating member which applies heat to the balloon simultaneously along the length of the balloon) and inflation of the balloon in a patient's vessel as part of a catheter system, the balloon is exposed to a shrinking treatment which causes the radial shrinkage. However, as set forth in Applicant's claim 26, the balloon is formed by a process such that the resulting radial shrinkage (i.e., the amount by which the inflated outer diameter of the finished balloon during use thereof is less than the inflated outer diameter of the balloon formed within the balloon mold) is minimized to less than 10% and is in fact less than the radial shrinkage which would result if the balloon was heat set non-uniformly.

Wang et al. does not disclose or suggest a balloon formed by a process which produces a balloon having radial shrinkage which is less than 10% and which is less than the radial shrinkage which would result if the balloon was heat set non-uniformly.

The Examiner further states that the balloons of Wang et al. have been heat set in the balloon molds placed in hot water baths providing substantially uniform heating at 90 or 95 °C. However, Wang et al. discloses that the balloon mold is gradually dipped into a hot water bath, and after the balloon is formed, the mold is removed from the hot water

bath. Wang et al. does not disclose or suggest that after the balloon is formed, the balloon is exposed it to a heat setting procedure sufficient to heat set the balloon and reduce radial shrinkage caused by a subsequent shrinking treatment, or the importance of uniformly applying heat simultaneously along the length of the balloon.

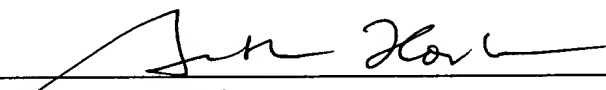
Applicants have amended claim 26 to obviate the rejection thereof under 35 USC 112, second paragraph, and have amended claim 31 to obviate the objection thereto.

Applicants wish to bring to the attention of the Patent Office the reference listed on the attached PTO-1449, and request that it be considered by the Examiner. This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(b)(4), and therefore no fee is due

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,

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